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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,244	01/18/2005	Scott K. Kuwada	21101.0026P1	7587
23859 7590 08/14/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER PAGONAKIS, ANNA	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 08/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/505,244

Applicant(s)

KUWADA, SCOTT K.

Examiner

Anna Pagonakis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 53-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1, 8-21, 26-57, 64-72 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

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### *DETAILED ACTION*

The following is responsive to applicant's remarks received on May 21, 2007. Applicant's election with traverse of Group I, claims 1, 18-21, 26-27 will be examined. Applicant's remarks concerning the previous restriction are not found persuasive. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the use of an NF- $\kappa$ B inhibitor as a therapeutic target for cancer is not novel (Biswas, Debajit. *PNAS*. 2001). Therefore, a holding of lack of unity amongst the inventions of Group I and II is proper.

Upon further consideration of the claims, the examiner respectfully submits the following supplemental restriction requirement.

Due to the complex nature of the claims, no request for an oral election is being made. Please see MPEP § 812.01.

### *Change of Examiner*

The examiner assigned to the instant application has changed. The new examiner is Anna Pagonakis. Contact information is provided at the end of this Office Action.

### *Election*

This application contains claims directed toward more than one species of the generic invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define one molecular structure for the NF- $\kappa$ B inhibitor. Currently, claims 32-38, 43, 44 and 47 are generic. Applicant is required to choose a specific NF- $\kappa$ B inhibitor from claims or pages 19-20 in the specification. If applicant elects a specific compound not found in the instant disclosure as filed, specie election may be considered new matter.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claims is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve the right to petition, the election must be made with traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of the species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in rejection under 35 U.S.C. 103(a) of the other species.

*Election Proper*

MPEP § 809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The present claims are directed to a method of inhibiting cancer cell proliferation. Present claim 36 for example provides a variety of possibilities for  $R^2$ ,  $R^3$  and  $R^4$ . For hypothetical exemplification only, if each of the variables above were each limited to 10 possible moieties there would be  $10^3$  possible species of compounds to be searched. Clearly, then, the species are drawn compounds having structurally divergent formulae. There are also additional species listed in specification pages 19-20 bridging paragraph.

Further, as shown by the following classifications, a majority of combinations encompassed by the present claims has acquired a separate status in the art. For example, if B is a ring comprising 1 N it is classified as in class 514 subclass 277, whereas if B is a ring comprising 2 N's it is classified as in class 514 subclass 247. Notwithstanding that the

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classification of some of the active agents is co-extensive, all of the claimed compounds are patentably distinct and fully capable of supporting separate patents.

The inventions above are patentably distinct. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim set for clarity, enablement and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicate above is deemed proper.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claims as provided by 37 CFR 1.141. If claims are added after the election, applicant must include which are readable upon the elected species. MPEP § 809.02(a).

#### *Sequence Rule Non-compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, line 2 page 59 of the specification. However, this application fails to comply with the

requirements of 37 CFR §§ 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

#### *Inventorship Notice*

Applicant is reminded that upon the cancellation of claims to an non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.148(b) if one or more of the currently named inventors is no longer an inventor of at least claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pagonakis whose telephone number is 571-270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

 8/11/07  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER